Utility of Vivosonic Integrity™ ABR system as a hearing screening device for children who are difficult to test

Capstone Project

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ABSTRACT

Hearing screenings are an important tool to determine when an individual is at a higher risk of having hearing loss. It is especially important to identify at risk individuals in the pediatric population, due to the significant impact that undetected hearing loss may have on language and educational development. Currently, methods exist to effectively screen most typically developing children. However, there is a lack of screening methods for children who are difficult to test, such as those with developmental disabilities. The current study compared referral rates from hearing screenings of preschool and school-aged children in a program that used traditional behavioral methods alone, with one using the Vivosonic Integrity™ ABR device in conjunction with behavioral methods. The study demonstrated that use of the Vivosonic Integrity™ ABR device as a hearing screener for difficult-to-test children results in significantly fewer referrals for comprehensive audiologic evaluation. The availability of a valid screening device for this population has the potential to save resources and provide valuable information on a child's hearing status that may otherwise be unavailable. Further research is indicated to assess the reliability and validity of the Vivosonic Integrity™ as a hearing screener for difficult-to-test children.

DEDICATION

To my best friend, Stephen, for the unending love and support he gave through the trials that led to this accomplishment.

To my mentors, Gail and Christy, who shaped me into the clinician and the professional I am proud to be.

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CHAPTER 1
INTRODUCTION

Hearing screening is an important and valuable tool in the identification of undetected hearing loss, especially for the pediatric population. Hearing screenings are differentiated from hearing assessment in that an assessment is intended to determine an individual's hearing status, while a screening is a "pass/fail" tool intended to determine whether a full assessment is warranted. Results of a hearing screening provide information on whether or not the individual has a higher potential to have a hearing loss. If results indicate that they are at a higher risk for having a hearing loss, the individual is referred for further assessment. If results indicate that the individual is unlikely to have a hearing loss, no further assessment is indicated. The benefit of performing a hearing screening is that it provides information in a cost-effective, efficient manner with minimal risk to the individual being screened (discussed further in later sections).

In order to develop an effective screening program, the prevalence of hearing loss in the population of interest must be considered. For example, the prevalence of hearing loss of any type or degree has been reported at 14.9% in 6-19 year olds (Niskar et al., 1998)—much higher than the 0.6% identified at birth (Prpić, Muhalja-Stamenković, Bilić, & Haller, 2007). In addition, the prevalence of hearing loss in children with developmental disabilities is reported to be significantly higher than in the general population (Roizen, Wolters, Nicol, & Blondis, 1993; Rosenhall, Nordin, Sandström, Ahlsén, & Gillberg, 1999). Rosenhall and colleagues (1999) found a prevalence of permanent bilateral hearing loss, of at least a mild degree, in children diagnosed with an Autism Spectrum Disorder (ASD) of 11.4%, which far exceeds the prevalence estimated for all children of 0.4% (Niskar et al., 1998). In a reverse study, investigators found that 1 in 59 children with hearing loss also carried a diagnosis of ASD (Szymanski, Brice, Lam,

& Hotto, 2012). This, again, is much higher than the national prevalence of ASD, which stands at 1 in 88 (CDC, 2012a). Based on these prevalence rates, the importance of periodic hearing screening of all children beyond that provided with Universal Newborn Hearing Screening is indicated.

Countless studies have demonstrated the importance of early identification of hearing loss, and the negative impact of undetected hearing loss on the development of speech, language, and literacy in children, as well as on their social and emotional development (e.g. Davis, Sheppard, Stelmachowicz, & Gorga, 1981; Blair, Peterson, & Viehweg, 1985). These negative effects are reported even for mild degrees of hearing loss, which may be easily overlooked in children (Bess, Dodd-Murphy, & Parker, 1998; Yoshinaga-Itano, DeConde Johnson, Carpenter, & Stredler Brown, 2008). Early identification and treatment has been found to result in better outcomes for children with hearing loss, particularly in the area of language development (Yoshinaga-Itano, Sedey, Coulter, & Mehl, 1998). However, to have periodic comprehensive hearing evaluations for every child would be impractical, both economically and logistically. Therefore, it is imperative that methods utilized to screen the hearing of the pediatric population be optimally reliable and efficient. Appropriate methods must be available not only for typically developing children, but also for children with developmental disabilities who may be labeled as "difficult to test" due to limitations in cognition or language, or challenging behaviors that limit the ability to obtain reliable screening results through conventional means.

EFFECTIVE SCREENING

In order to determine an appropriate hearing screening method for the difficult-to-test population, the term "effective screener" must first be defined. Guidelines for screening, outlined in a seminal text, were published by the World Health Organization (WHO; Wilson &

Jungner, 1968). This document defined a screener as a non-diagnostic tool that differentiates "apparently well persons who probably have a disease from those who probably do not" (Wilson & Jungner, 1968, p. 11). Therefore, a screener is not designed to identify the presence of a disorder, rather to identify an individual who is at higher risk for having a disease or disorder, and the consequent need for more extensive testing. Furthermore, screening is inappropriate for individuals who are known to have an increased risk for a particular disorder, such as those with associated signs and symptoms, or who have been previously identified. These individuals are referred directly to a full diagnostic examination without an initial screening test. Wilson and Jungner (1968) described the purpose of screening as the prevention of a pathological change in the individual. This is accomplished through early intervention, which may be sought following diagnosis confirmed after a failed screening.

Wilson and Jungner (1968) defined a series of key properties of a screening test, namely validity, reliability, yield, cost, acceptance, and follow-up services. Validity was defined as the ability of a test to correctly differentiate individuals who have a disorder from those who do not. A certain margin of error is inherent to any evaluation, and therefore some disorder-free individuals will be identified as positive for the disorder and vice versa. The ability of a test to correctly identify individuals as positive for a disorder is termed the sensitivity, or true-positive rate, of the test. The ability of a test to correctly identify disorder-free individuals as negative is termed the specificity, or true-negative rate, of a test. Ideally a test would have a very high sensitivity and a very high specificity. In reality, these calculations have a trade off with one another. Expanding pass/fail criteria to pass more individuals would decrease the sensitivity (by missing more disordered individuals) and also increase specificity (by decreasing the false-positive rate). Applying stricter criteria to a test would increase the number of individuals

SENSITIVITY/SPECIFICITY TABLE

	Positive Result (fail screen)	Negative Result (pass screen
Disordered Individual	True Positive	False Negative
Disorder-free Individual	False Positive	True Negative

Table 1: Sensitivity = (# of true positive)/(# of all disordered individuals screened);
Specificity = (# of true negatives)/(# of all disorder-free individuals screened)

identified as having a disorder. This will both decrease the specificity and increase the sensitivity. For example, in the current study, a static admittance value falling within the range of 0.3–1.4 mmho would result in a "pass" on the tympanometric screening for middle ear disorder. If this criterion were changed to 0.5-1.4 mmho, children with a static admittance of 0.3 or 0.4 would now be considered a "fail/refer". This change would result in more referrals, and a subsequent increase of sensitivity and decrease in specificity. A balance must be reached between the sensitivity and specificity so that the evaluation identifies most individuals who have a disorder without having an excessive false-positive (or in the case of a screening, false-refer) rate. The American Academy of Audiology (2011) reported that in order for a hearing screening tool used for children 6 months of age thru high-school to be considered accurate, it should have sensitivity and specificity rates of at least 90%. FitzZaland and Zink (1984) found a sensitivity of 100% and a specificity of 97% in a screening program that used a combination of pure tone screening and tympanometry. See Table 1 (page 4) for a visual description of the relationship between sensitivity and specificity.

Reliability refers to the amount of variability in results. Test-retest reliability specifically refers to the variability between results of the same individual evaluated multiple times ("Reliability", n.d.). Essentially, if an individual fails a screening using a reliable measure, that same individual would be expected to fail a rescreening with the same measure (in the case of hearing, one must assume that the disorder is still present, which may not be true in the case of certain pathologies such as middle ear effusion). The reliability of a screener is influenced by the test itself, and by the individual performing the test. For example, if the individual performing a hearing screening is positioned in a way that the child can see when a tone is being presented (e.g. the child can see the presentation button being pressed) that child may pass, even if they

cannot hear the tones. If that screening were then repeated on the child when they could not see the presentation button, the results may change even though the child's hearing status did not. Test parameters and pass/fail criteria must be strictly set before screening begins. The screener should be quick, simple, and efficient to minimize the risk of user error or participant discomfort and subsequent increased variability (AAA, 2011; ASHA, 1997).

The yield of a screening is the number of previously unidentified individuals who were referred for and completed a comprehensive evaluation following a failed screening, diagnosed with the disorder in question, and received intervention services (Wilson & Jungner, 1968). In essence, the yield of a screener is the measure of its benefit to society. The yield will be higher in areas where the prevalence of a disorder is high, and the medical care available is minimal. Therefore, the yield is not only a measure of the quality of the screener, but also of the need for the screening test, and the need for effective follow-up services.

Cost of implementing a screening program, including that related to the equipment, facilities, and personnel, must be considered in a discussion of its value to society. The cost of the screening, combined with the cost of follow-up assessments and treatment, should not outweigh its benefit to the general population (Wilson & Jungner, 1968). That is, the costs associated with early identification and treatment of a disorder should be less than the cost of identifying the disorder in "natural" time (when symptoms have become pervasive and blatantly apparent) and intervening then. Gross (2007) reported that identifying hearing loss at birth and providing early intervention reduces the education costs of an individual child by $44,200. This demonstrates a considerable cost-benefit of identifying hearing loss early in children.

In order for a screening to be effective, it must be acceptable to the population being screened. It should be minimally invasive and avoid causing embarrassment to the individual.

Additionally, any risks associated with the screening, including emotional distress, must be minimized, if not eliminated. Finally, an efficient screener, with little time commitment required of the person being screened, is preferable.

A screening protocol is only valuable if it leads to appropriate referral, which in turn leads to appropriate diagnosis and treatment of hearing loss. Therefore, procedures for follow-up must be determined prior to the onset of screening. Referral sources must be in place and diagnostic and treatment options must be available within a reasonable distance of the site of screening. Methods, such as tracking individuals who fail a screening and sending reminders to follow-up with a comprehensive evaluation if necessary, should also be implemented to ensure compliance with recommendations (AAA, 2011; ASHA, 1997).

Current screening methods for infants and typically developing school-aged children, when implemented in an appropriate environment with well-trained personnel operating the equipment, are acceptable in terms of the WHO guidelines (FitzZaland & Zink, 1984; Wilson & Jungner, 1968). They render an acceptably high level of validity, and methods have been found to be reliable, cost-effective, and acceptable when implemented according to current guidelines (AAA, 2011; ASHA, 1997). However, reliability and validity come into question when screening school-aged children with developmental disabilities. This is because methods have yet to be evaluated and implemented for this population.

The present study investigated a new screening option that is purported to be effective for the difficult-to-test population. Because the present study focused on screening, rather than comprehensive evaluation and diagnosis that follow a failed screening, the issues of reliability, validity, yield, and follow-up will not be addressed. The study attempted to address the issue of acceptance of the screener through observation of participant reaction. Cost was also addressed

in terms of resources that may be saved by reducing referrals that result from an inability to screen a child using traditional behavioral methods.

CHAPTER 2
REVIEW OF THE LITERATURE

CURRENT SCREENING METHODS: UNIVERSAL NEWBORN HEARING SCREENING

Currently, universal newborn hearing screening (UNHS) is performed at birth. In addition, children in public schools receive hearing screenings at several intervals throughout their schooling, as mandated at the state level. The Joint Committee on Infant Hearing (JCIH) 2007 Position Statement states that all infants should have a hearing screening before 1 month of age (JCIH, 2007). This is accomplished through UNHS occurring at hospitals nationwide. In 2010, 97.4% of all infants born in the US were screened for hearing loss, amounting to 3,803,067 hearing screenings performed that year (CDC, 2012b). Newborn hearing screening is executed utilizing electrophysiologic methods, namely, Otoacoustic Emissions (OAEs) and the Auditory Brainstem Response (ABR). It should be noted that both OAEs and ABR can be used for both diagnostic and screening purposes. When utilizing these methods for diagnostic purposes, testing is more extensive, assessing multiple discrete frequencies at multiple input levels, and is interpreted in conjunction with other tests as part of a comprehensive evaluation. When using these methods for screening purposes, the protocol is typically limited to pass/fail judgments, evaluating a broad frequency range as a whole to determine whether or not the individual has a higher likelihood for hearing loss and therefore requires subsequent testing.

OAEs are outputs emitted from the cochlea as a result of the electromotile responses of outer hair cells to presented acoustic stimuli (Shera & Guinan, 1998). Following acoustic stimulation, outer hair cells produce a non-linear response, which results in a backward-traveling wave that can be recorded from the ear canal. These responses are recorded from the ear canal using a noninvasive probe microphone. The presence of OAEs indicates that outer hair cells

within the cochlea are functioning normally, as is the middle portion of the conductive auditory system (Kemp, 2002). Abnormal outer hair cell function is the most common cause of sensorineural hearing loss (Raphael, 2002), and middle ear disease is the most common cause of pediatric hearing loss (Eagles, Wishik, & Doerfier, 1967; Simpson et al., 2010). Therefore, normal OAE responses are a strong indicator of normal hearing function. When using OAE's diagnostically, one may interpret each frequency independently to determine presence or absence of a response at each discrete frequency. When using OAE's as a screener, one may allow an overall "pass" result with the presence of OAE's at a fraction of the total frequencies assessed (AAA, 2011).

ABR is an electrophysiologic response originating in the brainstem. Neural activity occurs as sound is transmitted from the ear level to the cortical level, where is it decoded and eventually realized as sound by a normal hearing listener. ABR equipment records this activity and displays it in a waveform, which can then be analyzed for any abnormalities. This electrophysiologic response is recorded using electrodes placed strategically on the scalp, typically one or two on the forehead or scalp, and one behind each ear. Stimuli are presented via headphones or insert earphones, and electrical activity emanating from the brainstem in response to the acoustic stimuli is recorded as a waveform. Analysis of the ABR typically focuses on the first five waves, each reflecting energy from a different generator site (Wave I: Auditory Nerve, Waves II & III: Cochlear Nucleus & Superior Olivary Complex, Wave IV & V: Lateral Lemniscus & Inferior Colliculus; Starr & Hamilton, 1976). Because the ABR is a bioelectrical response from the brain, it occurs in a background of other similar electrical activity like electroencephalographic (EEG) activity, and electromyographic (EMG) activity (Mason, McCormick, & Wood, 1988). Additionally, extraneous electrical activity, such as that generated

by a nearby light or computer, can interfere with the recorded response. ABR equipment utilizes various techniques to reduce the "noise" resulting from internal and external electrical activity. These techniques include filtering of the recording to include only the expected response spectrum, signal averaging to eliminate random noise, and utilizing an appropriate stimulus paradigm (Delgado & Ozdamar, 2004; Granzow, Riedel, & Kollmeier, 2001; Riedel, Granzow, & Kollmeier, 2001). While these measures do improve the signal-to-noise ratio (SNR) of the response, the electrical noise must still be controlled as much as possible. In order to obtain a useful ABR waveform, it must be recorded on an individual that is relatively quiet and still, and in a room with little electrical interference. Presence of an ABR response indicates that the acoustic signal has traveled successfully through the pathway from the external ear to the brainstem. It does not indicate functional hearing, as there is the possibility that a lesion may exist at the cortical level, beyond the recording site. For example, an individual with dysfunction in their auditory cortex may still have normal activity of the cochlea and auditory nerve, and therefore still have a normal ABR without being able to hear. However, the ABR does indicate that several segments of the auditory pathway, including the hair cells within the cochlea, the auditory nerve, and the cochlear nucleus, are functioning properly. Therefore, a normal ABR does correlate with normal hearing. Additionally, when performing a diagnostic ABR (as opposed to a screening ABR), various morphological markers found in a disordered ABR waveform are correlated with specific types of hearing loss. Therefore, an ABR waveform can provide more information than whether or not a hearing loss exists. It can suggest where, on a disordered auditory pathway, the dysfunction is occurring. See Image 1 (page 12) for an example typical ABR waveforms.

TYPICAL ABR WAVEFORMS

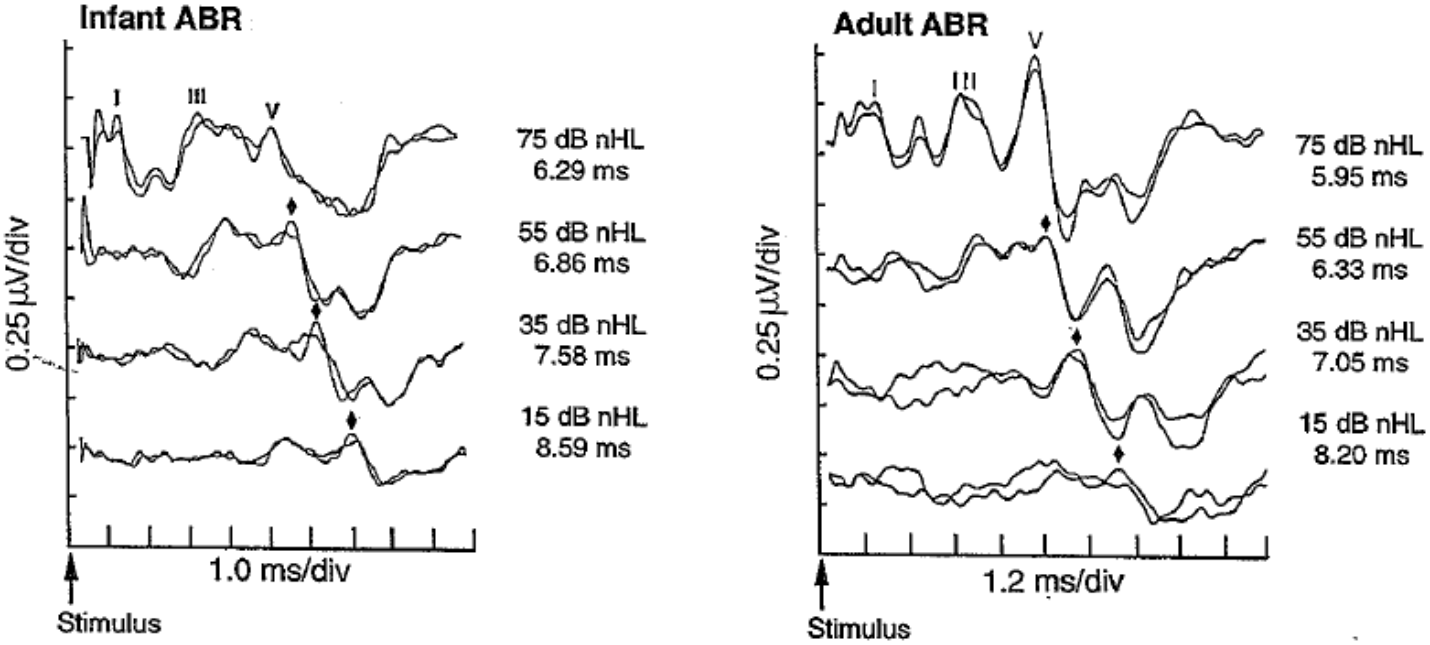

Image 1: Typical ABR waveforms of infant and adult individuals at various intensity levels (Hood, 1998).

Both OAEs and ABRs have been used as effective screening methods for the infant population (JCIH, 2007). These methods do not require active participation from the listener, and therefore are able to provide results even for individuals who may otherwise be difficult to test. As stated previously in relation to ABR, these methods, unlike behavioral assessment, do not indicate normal hearing, merely the active functioning of the segments of the auditory system they evaluate. However, as a screener, this does accomplish the goal of determining whether the child is at a higher risk for having a hearing loss, by ruling out several of the common causes of childhood hearing loss (e.g. middle ear dysfunction, outer hair cell dysfunction, auditory nerve dysfunction). Additionally, ABR screenings performed at birth typically utilize a broadband click stimulus, which, although it does encompass the greatest range of frequencies, does not provide frequency specific results. The range of frequencies tested by the ABR and OAE stimulus is relatively narrow and restricted to the basal half of the cochlea. Therefore, a child with a more atypical hearing loss, focused solely in the high- or low-frequency range, may pass these screenings. Finally, because UNHS are performed close to birth, they will miss any hearing loss that has a late onset or is progressive in nature.

It is also important to recognize the significance of proper follow-up protocol for children who do not pass the hearing screening. If these children do not go on to receive a comprehensive evaluation, followed by treatment if necessary, then the value of the screening is lost. JCIH (2007) recommends a hearing screening by 1 month of age, followed by a comprehensive evaluation by 3 months of age for those children who do not pass the initial screening. Those children who are diagnosed with hearing loss should receive treatment by 6 months of age.

CURRENT SCREENING METHODS: PRESCHOOL AND SCHOOL-AGED SCREENING

As discussed previously, hearing screenings are mandated by state departments of health or education (depending on the state) to occur at several intervals throughout schooling for all students of public schools. Therefore, a late onset or progressive hearing loss is likely to be identified during childhood if appropriate hearing screening is performed. However, due to the potential for significant negative outcomes with an untreated hearing loss, it is valuable to identify hearing loss as early as possible.

Requirements for school-aged hearing screenings are regulated at the state level. In Ohio, hearing screenings are required at the beginning of each year that a child attends a public or special needs preschool program, and at the start of kindergarten, first, third, fifth, and ninth grades (Ohio Department of Health [ODH], 2007). The ODH mandates that hearing screening be performed utilizing pure tone audiometry with a behavioral response. The American Speech-Language-Hearing Association outlined a standard protocol to be used for childhood hearing screening (ASHA, 1997). The child listens to tones presented via headphones and must respond, either verbally (e.g. "I heard it") or physically (e.g. raising hand), indicating that they heard the tone. Pure tone stimuli are presented to each ear individually at 500Hz (if tympanometry is not used), 1000Hz, 2000Hz, and 4000Hz at an intensity of 20dB HL (ODH, 2007). If the child does not respond to any one tone in either ear, they did not pass the screening, and must be rescreened within four to six weeks. If the child does not pass the rescreen, they are to be referred for a comprehensive medical and audiologic evaluation. Guidelines for school hearing screenings also stipulate that special needs students that are unable to be screened must be referred for a complete medical and audiologic evaluation.

Traditional behavioral methods are effective for screening the hearing of typically developing school-aged children, as determined by their high sensitivity and specificity rates (FitzZaland & Zink, 1984). However, for some children, especially those with developmental disabilities, a nontraditional method may be necessary to achieve reliable results. The Pilot Audiometer™ may be an alternative to traditional pure tone screening. Although this method is not explicitly supported by the ODH guidelines, it has been used successfully as a hearing screener for young children (Crowley, Bains, & Pellico, 2005). The Pilot Audiometer™ incorporates speech stimuli (spondees), rather than pure tones, and the child responds by pointing to a picture of the spondee displayed on the console of the audiometer. The Pilot Audiometer™ is marketed as being an ideal screening tool for young children because the speech stimuli and interactive "game-like" test procedures are able to hold their attention (Maico Diagnostics, 2011). Additionally, as with other screening methods, ear specific information may be obtained when using headphones or insert earphones. However, because the Pilot Audiometer™ uses speech stimuli, frequency specific information is not provided. Therefore, a hearing loss focused in the low- or high-frequency range may be missed. Reliability data for the Pilot Audiometer™ is unavailable, and so it is unclear whether this device is as effective at screening for hearing loss as conventional methods.

ASHA (1997) recommended that hearing screening be performed using conditioned play audiometry (CPA, in which the child is conditioned to perform an action, such as drop a block into a container, whenever he/she hears a tone), or conventional audiometry by 5 years of age. Therefore, pure tone screening methods and the Pilot Audiometer™ are both appropriate for screening typically developing school-aged children. A benefit of these behavioral methods over the electrophysiologic methods discussed above is that they evaluate the functional hearing

abilities of the child. When a child passes a behavioral hearing screening, it indicates that they have a low probability of having a hearing loss. Unfortunately, behavioral screening methods may be inappropriate for some children, due to cognitive deficits or behavioral issues that result in the child being unable to perform the required tasks. For these children, an objective screening method would be preferred to obtain reliable results.

There are many challenges associated with both ABR and OAE screening of the school-aged population. For example, movement and vocalization can interfere with results, and therefore they are routinely performed for infant hearing screening while the newborn baby is sleeping. Both OAE and ABR may be influenced, or become unrecordable, in the presence of middle ear fluid. Therefore, it is important to perform tympanometry, a noninvasive measure of middle ear function utilizing pressure presented to the ear canal, prior to OAE or ABR testing. Finally, ABR and OAE test equipment may not be available at typical audiology practices, or may only be available for diagnostic purposes, and is often not portable. Therefore, access to this objective testing may be limited to hospitals only. Performing hearing screenings in the schools provides a captive audience, and ensures that screening is attempted on most, if not all, children. Therefore, it would be beneficial if all students, even those that cannot perform tasks required of behavioral screening, could be screened in this setting.

SCREENING CHILDREN WHO ARE DIFFICULT TO TEST

Some children, such as those with developmental disabilities, are unable to provide reliable behavioral responses or any behavioral responses at all. These children, often termed difficult-to-test, cannot be screened using traditional methods due to unreliability, an inability to understand and complete the task, or being otherwise uncooperative with the screening (e.g. refusing headphones). These children are to be referred for a comprehensive evaluation in the

state of Ohio, as mandated in ODH guidelines for school-aged hearing screening (ODH, 2007). However, to repeat a comprehensive evaluation every few years on a child with no history or indication of hearing loss may be an inappropriate use of resources. Additionally, if the child cannot complete a behavioral screening, it may be unrealistic to expect that they would perform the tasks necessary for a traditional audiologic evaluation. As discussed above, the objective evaluation methods currently utilized require the individual to be calm and cooperative, and therefore are also unreliable for the school-aged difficult-to-test population. Sedation is available to improve testability, but is undesirable for many reasons, including associated costs and risks to the patient (discussed further below). The current screening methods available, which are relatively unchanged since their inception, do not accommodate these vulnerable individuals.

Although unidentified hearing loss is a concern for children in general, it is of greater focus in those with developmental disabilities. A number of studies have found that children with developmental disabilities are at a higher risk for hearing loss than their typically developing peers (Roizen, Wolters, Nicol, & Blondis, 1993; Rosenhall, Nordin, Sandström, Ahlsén, & Gillberg, 1999). Additionally, the behavioral manifestations of some developmental disorders may initially be mistaken as being caused by hearing loss and vice versa (ASHA, 2006). In order to ensure proper diagnosis and appropriate intervention, it is essential that a child's hearing status be determined. Without this knowledge, a child may not receive optimal benefit from intervention techniques, or may be misdiagnosed and thus receive an entirely inappropriate intervention.

While behavioral hearing screening is effective for typically developing children, some children are unable to be screened in this manner. This may be due to a number of factors including that the child has limited language ability, impaired cognitive status (e.g. inability to

understand and perform the task), or is uncooperative (e.g., removing the headphones repeatedly, vocalizing during testing). If a child is unable to perform the tasks required for a behavioral hearing screening, they should be referred for a comprehensive evaluation (ODH, 2007).

As noted previously, OAE and ABR may demonstrate promising screening methods with this population because they do not require the active participation of the child. In an effort to obtain reliable and valuable information in individuals who are difficult to test, ABR with sedation is routinely used (Pillion, Bibat, & Naidu, 2010; Reich, & Wiatrak, 1996; Tas et al., 2007). While administering sedatives results in a quicker and more reliable ABR, it introduces additional risks and costs to the procedure. Costs associated with sedation include the cost of the utilized pharmaceuticals, those for additional equipment and personnel to monitor the child's level of consciousness, as well as equipment to resuscitate the patient if necessary (Robinson, 2000). Risks include apnea, vomiting, allergic response resulting in rash, and respiratory distress (Akin et al., 2005; Avlonitou et al., 2011). In rare cases, complications of sedation can result in permanent neurological injury or death (Coté, Notterman, Karl, Weinberg, & McCloskey, 2005). Not only is sedation undesirable due to the potential risks, it is also contraindicated for some children (Robinson, 2000). Additionally, sedation is often only available in hospital settings, limiting the access of these evaluations for many individuals. Some parents may be noncompliant with recommendations for a sedated ABR because of the potential risks to their child, or limited resources available to schedule this assessment (e.g. money, time, transportation, etc.). Therefore, reducing or eliminating the need for sedated testing is desireable.

LATER EVOKED POTENTIALS

Objective measures of hearing sensitivity may be essential, as the only source of information, when evaluating individuals who are difficult to test. Therefore, developing a method to accurately assess an individual's hearing sensitivity without sedation would be of paramount importance. Alternatives to sedated ABR have been attempted in the past, but typically only for diagnostic, not screening, purposes. Cortical evoked potentials, such as the auditory middle latency response (AMLR) and auditory late response (ALR), overcome some of the challenges associated with ABR. Because these responses have a longer latency, stimulus artifact does not contaminate the response as it sometimes can in ABR recordings. Additionally, the electrodes can be placed closer to the generator sites when recording the AMLR and ALR because they are located in the more superficially located cortex rather than the brainstem. This results in a larger response wave, and therefore a better signal-to-noise ratio (Hall, 2007). These later responses also have the added benefit of being generated in the cortex, and therefore provide a closer approximation of the individual's functional hearing ability. Unfortunately, studies have shown that later responses have more variability in children and are therefore more difficult to interpret. AMLR and ALR responses in children may result in very broad peaks or entirely absent peaks, and overall variable morphology, making estimation of hearing sensitivity speculative (Tucker & Ruth, 1996; Pasman, Rotteveel, Maassen, & Visco, 1999). Additionally, later evoked potentials are more difficult to perform and interpret for any population, and require esoteric knowledge of electrodiagnostics in audiology, making them a less practical choice for a standard screening method.

Another auditory evoked potential, the Auditory Steady State Response (ASSR), holds significant value in pediatric hearing assessment. One advantage of the ASSR is that it allows for

frequency-specific threshold estimation at levels in the profound hearing loss range (>90 dB HL), much higher than the maximum output allowable for other evoked potential testing (Hall, 2004). Additionally, ASSR uses a statistical analysis to determine the presence or absence of a response, and therefore does not require the evaluator to have experience with waveform analysis. These facts make ASSR a valuable tool for diagnostic audiology with pediatric patients. However, the ASSR, like other evoked potential testing, requires the patient to be still and calm to obtain usable results. Additionally, effects of sedation impact the ASSR, and interpretation of responses is difficult in sedated individuals (Hall, 2004). For these reasons, the ABR is the preferred evoked potential for the estimation of hearing sensitivity in young children who are difficult to test.

DEVELOPMENT OF ABR SCREENER FOR DIFFICULT-TO-TEST CHILDREN

While behavioral hearing screening is appropriate for typically developing school-aged children, children with developmental disabilities or those who fall into a category of children who are "difficult to test" may not be able to complete the tasks required to be successfully screened. Currently, there is a lack of screening options for this population, often resulting in referral for more expensive, yet unnecessary, diagnostic testing or in having the hearing screening needs overlooked and these children falling through the cracks. Historically, the ABR is well established as an effective screening method of auditory function. It is primarily utilized as a screener for the infant population, and is explicitly recommended for use in UNHS by the JCIH (2007). However, as noted previously, ABR is not typically used as a screening method for children beyond infancy because it requires the individual to be still and quiet during testing and the ABR equipment is generally not portable enough to use in environments in which screening often takes place, such as a school or community center. Additionally, ABR screening must take

place n a quiet test environment, which is not always an option in facilities in which screening will take place. The Vivosonic Integrity™ ABR system, a recently developed system that was approved by the US Food and Drug Administration (FDA) for use in 2005, may hold promise for use as a non-sedated electrophysiologic screening method for children who are difficult to test. The Integrity™ has obtained clearance for marketing and use by the U.S. Food and Drug Administration (FDA; 510(k) K043396) and the Federal Communications Commission (FCC; Product ID TVZ-V50). It is also currently approved by the appropriate entities for use in Canada and the European Union (Vivosonic, 2011).

The Integrity™ consists of 3 electrodes with leads that connect to a body-worn processor (see Images 2 and 3, pages 22-23). That processor then communicates via Bluetooth with the analysis computer. The design of Integrity™'s processor has been reported to reduce unwanted electrical noise (Sokolov, Kurtz, Steinman, Long, & Sokolova, 2006). As discussed previously, the ABR waveform occurs in a background of noise from external electrical devices (e.g. lights and computers) and internal bioelectrical activity (e.g. muscle movement). In order to obtain a usable ABR waveform, the signal (i.e. ABR waveform) must be significantly larger than the noise (i.e. internal and external electric activity). This difference, between the level of the signal and the level of the noise, is referred to as the signal-to-noise ratio. The Integrity™ improves the signal-to-noise ratio by reducing electrical noise in several ways. First, the Integrity™ utilizes a battery-powered processor and Bluetooth communication with the analysis computer, thus eliminating multiple wired electrical communications and the resulting noise. Because the electrodes must only communicate with the body worn processor, the leads are much shorter than those on a conventional ABR system, again reducing the potential for electrical interference. These leads are also encapsulated in airtight plastic, which is intended to further

shield the device from extrinsic electric and magnetic fields. While most ABR systems utilize a preamplifier at the distant end of the electrode leads (distal from the electrodes themselves), the Integrity™ utilizes

PHOTOS OF VIVOSONIC INTEGRITY™ DEVICE

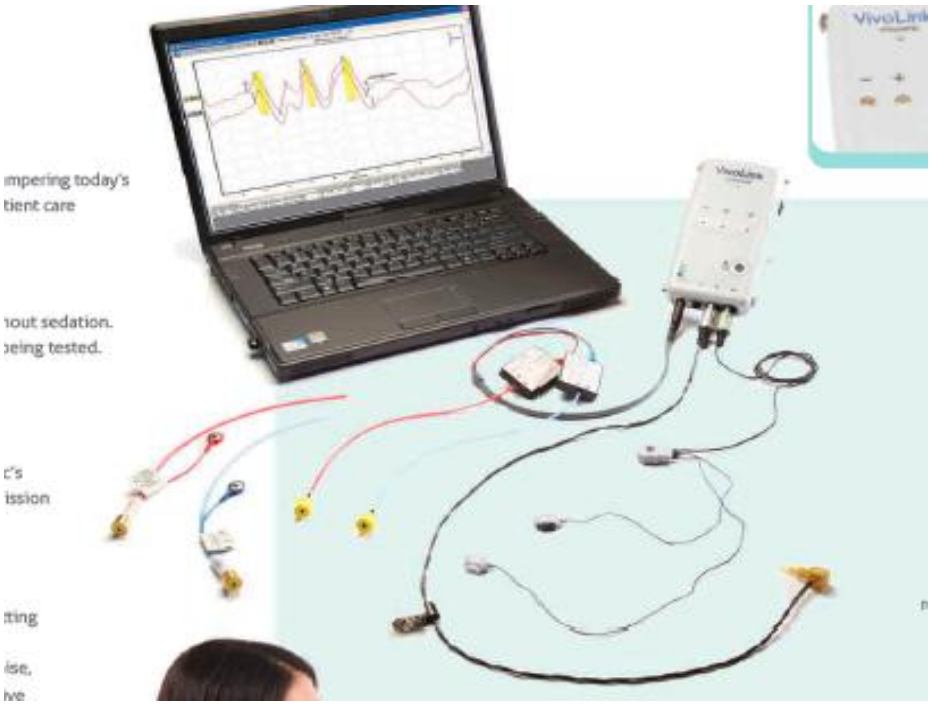

Image 2: Components of Vivosonic Integrity™ (Vivosonic, 2011)

Image 3: Vivosonic Integrity™ worn as a backpack (Vivosonic, 2011)

the Amplitrode™, a unique pre-amplification device. This device is contained in electrical shielding plastic and attached directly to the electrode clips. This results in the small ABR response being amplified prior to electrical interference that may occur as the signal travels from the electrodes to the analysis computer. The aforementioned features of the Integrity™ reduce extrinsic electrical noise. The device also has properties used to reduce internal electrical noise, such as EEG. This is done through filtering the response to include only those frequencies in which the auditory response would be expected to reside. In traditional ABR systems, the filtering occurs after the pre-amplification of the response. The response filter in the Integrity™ system is positioned within the Amplitrode™, prior to the preamplifier. This results in a reduction of noise contamination prior to pre-amplification, which allows for a more optimal amplification level. Finally, in order to reduce corruption of the response by EMG, the Integrity™ utilizes a Kalman-weighted averaging filtering system. Conventional ABR systems combat muscle artifact by averaging together multiple responses to eliminate the random noise, by rejecting responses that contain artifacts over a pre-determined level, and by simply pausing the recording and waiting for the individual to stop moving (Sininger et al., 2000). All of these methods extend test time and may be ineffective if the individual is unable to remain still. The Integrity™ system uses an averaging system that more heavily weights responses that have less artifact, resulting in what is intended to be a cleaner final product. In other words, the ABR waveform is more clearly visible and therefore analysis is possible. The unique features of the Integrity™ ABR, including the Amplitrode™ and Kalman-weighted averaging, are advertised as means for the system to significantly reduce noise in the response, resulting in the ability to obtain a clinically useful ABR response without the limitations of a more traditional ABR, such as the need to have an optimal testing environment or a quiet child. Additionally, unlike

traditional ABR systems, the Vivosonic Integrity™ is entirely portable, so it can easily be moved from site to site. Furthermore, it allows for the person being screened to move during the process, as they are only tethered to a device that is worn on their person.

Although use of the Integrity™ system holds great promise as a screening tool, the current manufacturer's claims regarding the success of the Integrity™ are based primarily on proprietary research with little independent peer-reviewed support. One study compared the utility of the Vivosonic Integrity™ ABR system with a conventional ABR system in evaluating the response of non-sedated individuals with cerebral palsy, who were classified as difficult-to-test due to motor or cognitive limitations, which impacted the ability to obtain consistent behavioral results (Westhuizen, 2010). Participants were screened for middle ear disorder prior to ABR assessment, and assessment was performed using both methods simultaneously to reduce contaminating variables. Results of this study revealed that electrophysiologic hearing thresholds could be obtained in 87% of the participants using the Vivosonic Integrity™ ABR system, and only 73% of the participants when using the conventional ABR system (Westhuizen, 2010). While these results were not statistically significant, they did demonstrate a statistical trend; the study was also limited by a small sample size of 15. Additionally, participants in this study exhibited sporadic movements during testing, which is comparable to the activity expected of the difficult-to-test participants of the present study. Therefore, these results suggest that the Vivosonic Integrity™ may be useful in obtaining results from other difficult-to-test populations, including children with developmental disabilities. Another independent study used archival data to retroactively compare the pass rate of infant ABR screenings using the Vivosonic Integrity™ and those using traditional ABR systems, specifically the Cadwell Sierra II™ and the GSI Audera™. This study, which included 952 participants over a five-year period, found no

significant differences between equipment type and pass rate (Lewis & Ramachandran, 2013). This suggests that the Vivosonic Integrity™ provides comparable hearing screening results to traditional ABR systems.

The purpose of the present study was to evaluate the utility of the Vivosonic Integrity™ ABR system as a screening method for preschool and school-aged children with developmental disabilities, who may be classified as difficult-to-test through conventional means. The current study was based on the general hypothesis that many of those children who are unable to be screened using behavioral methods would be able to be successfully screened with the Vivosonic Integrity™.

RESEARCH QUESTION

Can children with developmental disabilities who were unable to be screened for hearing loss using traditional behavioral methods be successfully screened with the Vivosonic Integrity™ ABR system?

HYPOTHESES

1. The number of children who could be assessed following part 2 of the study (which utilized electrophysiologic screening methods) would be significantly higher than following part 1 of the study (which used behavioral screening methods).
2. Referral rates from following part 1 of the study would be significantly higher than referral rates following part 2 of the study.

CHAPTER 3
METHODS

PARTICIPANTS

This study was approved by the Behavioral and Social Sciences Institutional Review Board at The Ohio State University. Participants in this study were 43 preschool and school-aged children recruited from a local preschool that educates children with developmental disabilities (primarily ASD) in Columbus, Ohio. Participants were recruited using parental permission forms distributed and collected by school personnel (see Appendix). Individuals did not receive monetary compensation for their participation. However, participants who completed the ABR screenings were provided a toy to keep following participation, and those students that failed the ABR hearing screening were provided with a referral for a complimentary comprehensive audiologic evaluation at The Ohio State University Speech-Language-Hearing Clinic.

Participants were 38 male and 5 female children, between the ages of 3.4 and 11.6 years (M = 6.4, SD = 2.4), recruited from the Helping Hands Center for Special Needs, a school in Columbus, OH. The study group included children diagnosed with developmental disabilities (primarily ASD) and typically developing peers. All participants underwent otoscopy, tympanometry, and behavioral hearing screenings. Those that did not pass the behavioral hearing screening also underwent an ABR screening with the Vivosonic Integrity™ System. The disproportionately larger number of male participants is likely a reflection of the gender imbalance noted in those diagnosed with ASD and other related developmental disorders (CDC, 2012a)

MATERIALS AND INSTRUMENTATION

Visual examination of the external auditory meatus and tympanic membrane was performed using a Welch Allyn Halogen Otoscope. Otoscopic examination was used to confirm

that the outer ear was free of debris, and that canals were clear and patent for later procedures (ABR assessment) that require the placement of an insert earphone in the ear canal (Diefendorf, 2009).

Evaluation of middle ear function was performed using a Micro Audiometrics Earscan ES-TR Tympanometer. This instrument was calibrated in September of 2011, in keeping with ANSI immittance specifications, which mandate annual calibration (ANSI S3.39-1987, R 2002). Tympanometry was used to confirm an intact tympanic membrane (i.e. free of perforations) and normal middle ear function. Appropriate tympanometric results were determined utilizing the 90% confidence ranges developed by ASHA, specifically an ear canal volume of 0.6–1.5 cc, and static admittance of 0.3–1.4mmho (Adapted from ASHA, 1990).

Behavioral screenings were completed using The Beltone Model 120 Audiometer with TDH-39 supra-aural headphones. This instrument was calibrated in September of 2011 in keeping with ANSI audiometer specifications, which mandate annual calibration (ANSI S3.6-2004). A listening check, in which the researcher confirmed that the frequencies to be tested are audible at 20 dB HL, was performed on the instrument prior to each screening session. ASHA (1997) and ODH (2007) approved methods for school-aged hearing screening were used to determine pass/fail status of the participant, as will be further discussed under Procedures.

ABR screening was completed using the Vivosonic Integrity™ ABR system with ER3-14B disposable foam insert earphones and Ambu Neuroline 720 electrodes, utilizing a click stimulus. This equipment was calibrated based on manufacturer recommendations. Equipment parameters were set based on recommendations in the Integrity™ User's Manual (Document 11049, Revision 5.1).

PROCEDURES

On the set screening date, an appropriate room was selected that had low ambient noise (determined by listening check), and the same setting was used for all screenings. Daily calibration measures were performed on all equipment. Each participant was screened individually, and only one participant was in the test room at any given time. Participants were often accompanied by school personnel, at the discretion of those personnel (e.g. some participants were more compliant with screening procedures with a familiar aide or teacher present). During screening, the personnel would assist with calming the child and getting them to attend to the task, when necessary. Standard methods were used for all screening procedures. All screenings were performed by the primary and co-investigators, with trained graduate students in speech/language pathology or audiology assisting

When the child entered the room, they were told what would happen. They were given a simple explanation, such as, “We are going to play a listening game.” Otoscopy was attempted on all participants. A standard otoscopic examination was performed following a simple explanation, such as, “I am going to take a look in your ear with my flashlight”. If otoscopy revealed that the ear canal was clear and the tympanic membrane could be visualized, this was noted and the child continued on in the study. If otoscopy revealed blocked ear canals, or if it could not be completed due to child behavior, this was noted, and the child still continued on in the study.

Tympanometry was attempted on all participants. A standard screening protocol was used, following a simple explanation, such as, “Now I’m going to take a picture of your ear with my special camera. Watch what it can draw.” The child was considered to be free of middle ear pathology if they passed the tympanometric screening, according to ASHA (1990) criteria. Any

child that failed the tympanometric screening was referred for a medical evaluation by an otolaryngologist. Costs associated with this evaluation were not covered by the present study. Participants were able to continue in the study regardless of tympanometric screening results.

A standard behavioral screening was then performed, using the audiometer. Children were given simple instructions, such as, "Now, we are going to play a listening game. You're going to wear these earmuffs, and I need you to listen really careful for a beep-beep sound. Every time you hear it, I want you to put your hand up in the air real high. Here we go!" The headphones were then placed on the child. The right ear was screened first. A 50dB HL 1000Hz tone was presented. If the child responded, it was immediately dropped to 20dB HL and re-presented. Next, a 1000Hz tone was presented at 20dB HL in the left ear, followed by a 20dB HL 4000Hz tone in the right ear, a 20dB HL 4000Hz tone in the left ear, a 20dB HL 2000Hz tone in the right ear, and finally, a 20dB HL 2000Hz tone in the left ear. If the child did not respond to any one tone, they were reinstructed with modeling of the desired behavior and rescreened immediately. An alternate response method was also utilized (e.g. asking child to give a high-five every time they hear the tone) for some participants. If the child responded to every tone presented at 20dB HL, they passed the screening, and their participation in the study was completed. If the child was uncooperative (e.g. refused to wear headphones or did not comprehend instruction), or could not perform the task (e.g. would not respond in a consistent manner to any tones presented, whether at 20dB HL or a higher intensity), they were classified as "Could Not Test (CNT)" and did not pass the screening. If the child did not respond to at least one of the tones presented at 20dB HL for each frequency in each ear, they did not pass the screening. These participants were referred for a follow-up ABR screening, to be completed in the same setting, on another date.

After obtaining parental permission for ABR screening for students who qualified to participate, as described previously, a date was set to perform ABR screenings. Again, the selected setting was assessed for low ambient noise, as estimated by the researchers. Daily calibration measures were performed on all equipment. Participants were screened individually. As stated previously, all screenings were performed by the primary and co-investigators, with trained graduate students in speech/language pathology or audiology assisting. Again, school personnel often accompanied the participant during the screening. Standard methods were used for all screening procedures.

When the child entered the room, they were given a simple explanation of what would happen, such as, "We are going to play a listening game." Prior to the start of the ABR screening, otoscopy and tympanometry were attempted using the methods listed above. Participants were first allowed to select a toy, provided as a reward. They were then given simple instructions regarding testing, such as, "We are going to put these stickers on your head and then you can play or watch a video while you listen to some silly sounds in your ears. Here we go." A beanbag chair was available for the child's use, to encourage comfort and relaxation during the ABR screening. Additionally, a computer was set up directly in front of the child, with a video that appealed to the child playing during set-up and screening. The purpose of the video and the toy was to distract the child from the task, so that they might be more cooperative, as well as to reduce any emotional discomfort or stress that the child experienced during acquisition of screening results.

A standard protocol was used regarding electrode placement and stimulus parameters. The child's skin was first wiped with an alcohol pad in the areas where electrodes were to be placed. Four electrodes were placed—two on the forehead (non-inverting (+) electrode on the

high forehead, ground electrode/Amplitrode™ on the low forehead), and one on the mastoid behind each ear (inverting (-) electrode on the test ear). Only three electrodes were actually in use at one time during testing (e.g. only the right-side mastoid electrode was used when testing the right ear). Following electrode placement, the ABR device was placed beside the child on a table, and insert earphones were placed in the child's ear canals. Each child was then presented with a click stimulus at 30dB nHL, in each ear. The purpose of using a presentation level of 30dB, rather than 20dB, is that auditory thresholds acquired with ABR have shown to be slightly elevated (approximately 10 dB) when compared with those acquired with behavioral methods (Stapells, Gravel, & Martin, 1995). Additionally, normative data are limited for response waves acquired using stimulus levels lower than 30dB nHL. Additional ABR parameters used are listed in Table 2 (page 33). The ABR waves were analyzed to determine pass/fail status following completion of all ABR screenings. Specific criteria used for this purpose are listed in Table 3 (page 34). ABR screenings lasted approximately 15-30 minutes per child. Any child that did not initially pass the ABR screening was rescreened immediately using identical parameters. Following completion of the ABR screening, electrodes were removed and the child returned to their classroom. They kept the toy as a reward for participating whether screening was completed or not.

Pass/fail status of each child on the screening was reported to school administrators so that they could share this information with parents. Children who failed the ABR screening were offered a referral for a complimentary comprehensive audiologic evaluation, to be completed at The Ohio State University Speech-Language-Hearing Clinic. A referral for a medical evaluation was provided for those students that were suspected of having outer or middle ear pathology.

SCREENING PARAMETERS

Stimulus Type	Click
Transducer Type	ER-3A insert earphones
Stimulus Rate (Stimuli/s)	37.7/sec
Maximum Number of Stimuli	Maximum
Windowing	Disabled
Ramp Number of Cycles	Disabled
High Pass Filter Cutoff Frequency	30 Hz
Low Pass Filter cutoff Frequency	1500 Hz
High Pass Filter Rolloff	12 dB/oct
Low Pass Filter Rolloff	24 dB/oct
Amplifier Gain	0
Recording Window	25 ms
Artifact Rejection	Disabled
Artifact Rejection Threshold	Disabled
Stimulus Level (dB nHL)	30 dB nHL
Algorithm	KalmanWeighted
Polarity	Rarefaction
Masker	Disabled
Masking Level	Disabled
Non-inverting (+)	Fz - Frontal Upper Forehead
Inverting (-)	A1 - Ear Lobe Left (if Left Ear is selected) OR A2 - Ear Lobe Right (if Right Ear is selected)
Recording Side	Ipsilateral
Notch Filter	Disabled
Electrode Used	Neuroline 720 000-S

Table 2: Screening parameters for ABR air-conducted click stimulus, adapted from Integrity™ User's Manual (Document 11049, Revision 5.1).

PASS/FAIL CRITERIA

	Absolute Latency Values		Interwave Latency Values
	Wave III	Wave V	III-V
Mean	5.45	7.24	1.74
SD	0.30	0.42	0.26

Table 3: Absolute and interwave latency values to be used as pass/fail criteria, adapted from Hood (1998), as recommended in Integrity™ User's Manual (Document 11049, Revision 5.1).

All records were stored at The Ohio State University Speech-Language-Hearing Clinic. Files are stored in a locked cabinet in a locked storage room, and will be kept for three years, in keeping with The Ohio State University Office of Responsible Research Practices standards.

CHAPTER 4
RESULTS

Consent could not be obtained for ABR screening for 1 participant, and his results were thus eliminated from data analyses, leaving 42 participants in the final analysis. A Chi-square analysis was used to assess gender and age effects. There were no significant gender or age effects for any screening results ($p > 0.05$).

Chi Square analysis was used to assess differences in the ability to screen participants following part 1 (behavioral screening) and part 2 (ABR screening) of the study. Behavioral screenings were completed on 24 participants (57%), with the other 18 (43%) recorded as CNT. Using the ABR screening for these 18 participants, results were obtained for an additional 10 participants (34 total participants with screening completed; 81%), leaving 8 participants (19%) labeled as CNT. There was a significant difference in the ability to test participants following part 1 and part 2 of the study ($p = 0.018$). A graphic display of ability-to-test data can be seen in Figure 1 (page 37).

Chi Square analysis was used to assess differences in the pass/refer rates following part 1 and part 2 of the study. Twenty-four participants (57%) passed the initial behavioral screening, with the other 18 (43%) referred for follow-up. Using the ABR screening for these 18 participants, an additional 6 participants passed the screening (30 total participants passed; 71%), leaving 12 participants (29%) referred for a comprehensive follow-up. There was no significant difference in the pass/refer rates following part 1 and part 2 of the study ($p >.05$). Examples of pass and refer ABR waveforms can be viewed in Images 4-8 (pages 38-42).

ABILITY-TO-TEST DATA

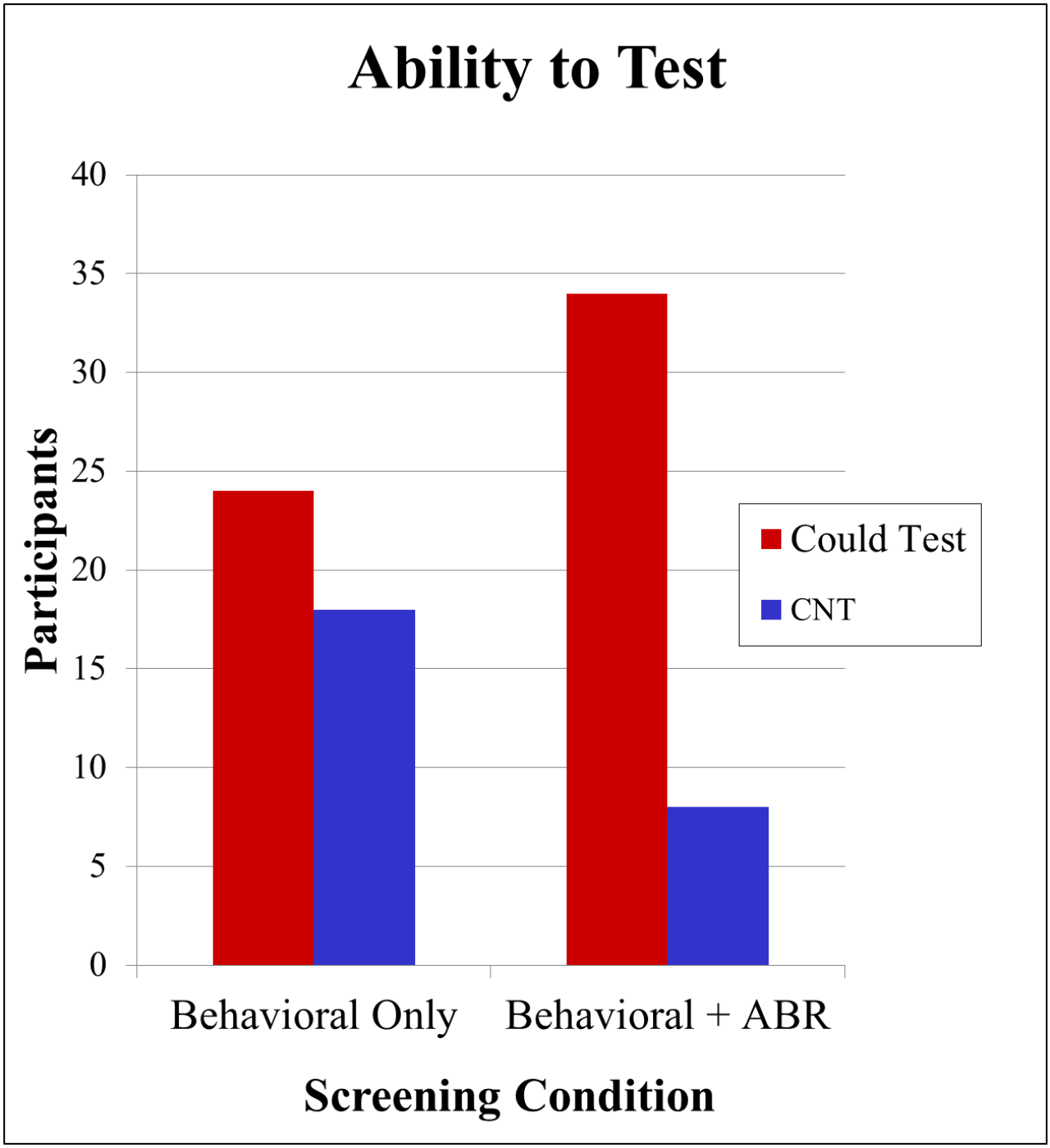

Figure 1: Significantly more subjects were able to be tested following behavioral + ABR screenings vs. following behavioral screenings alone.

PARTICIPANT WAVEFORMS

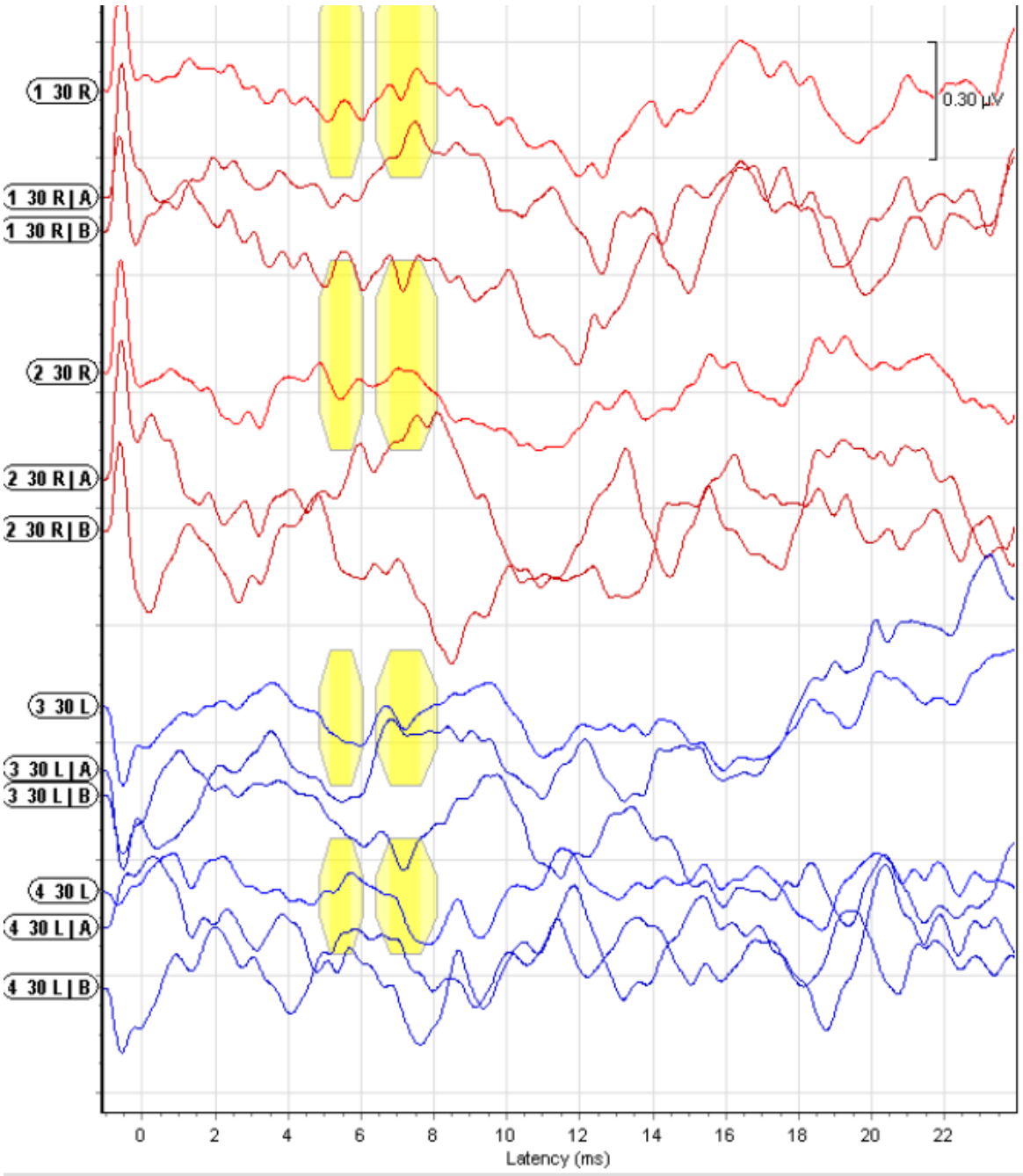

Image 4: ABR waveform from participant 26; fail in both ears.

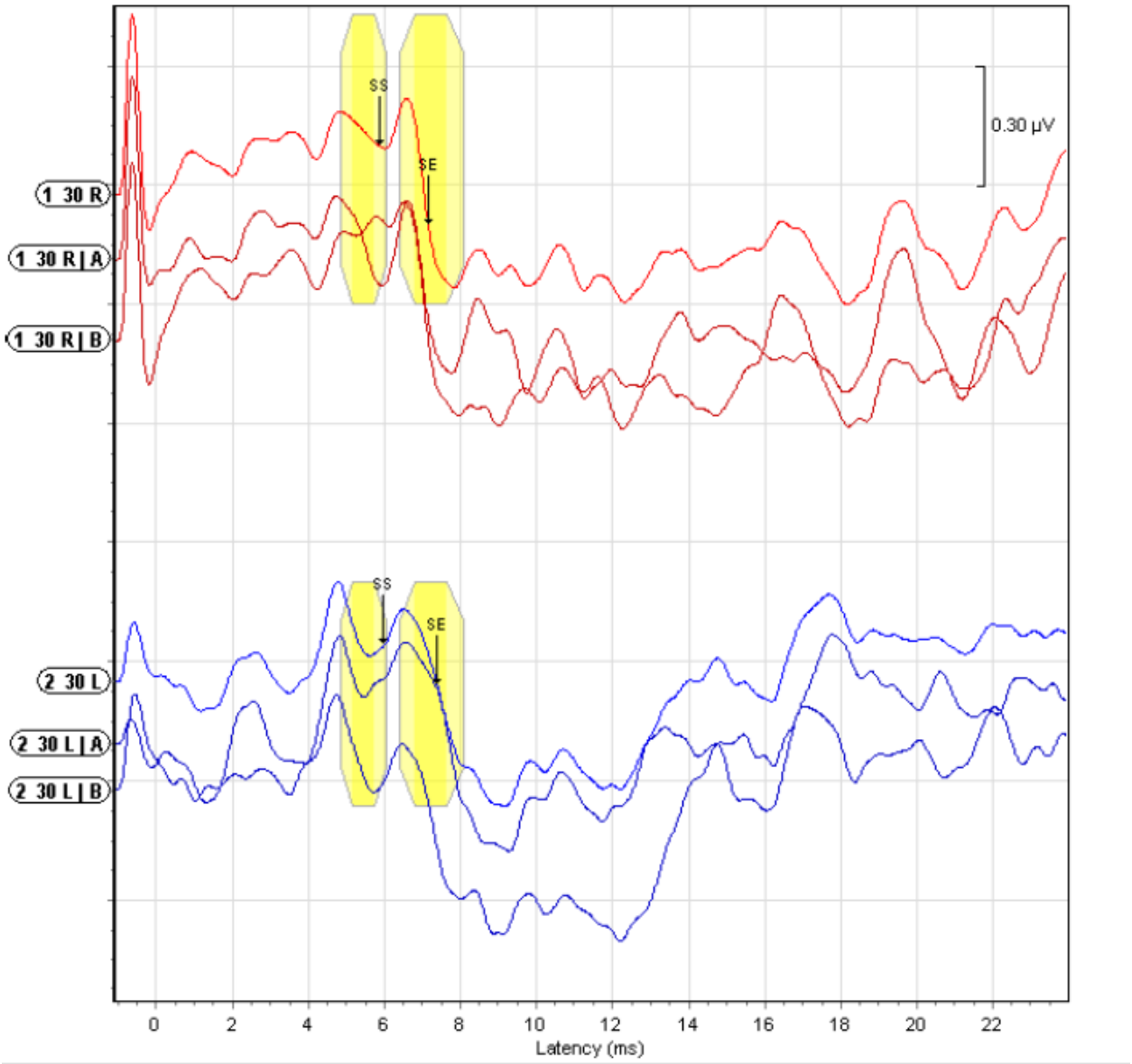

Image 5: ABR waveform from participant 214; pass in both ears.

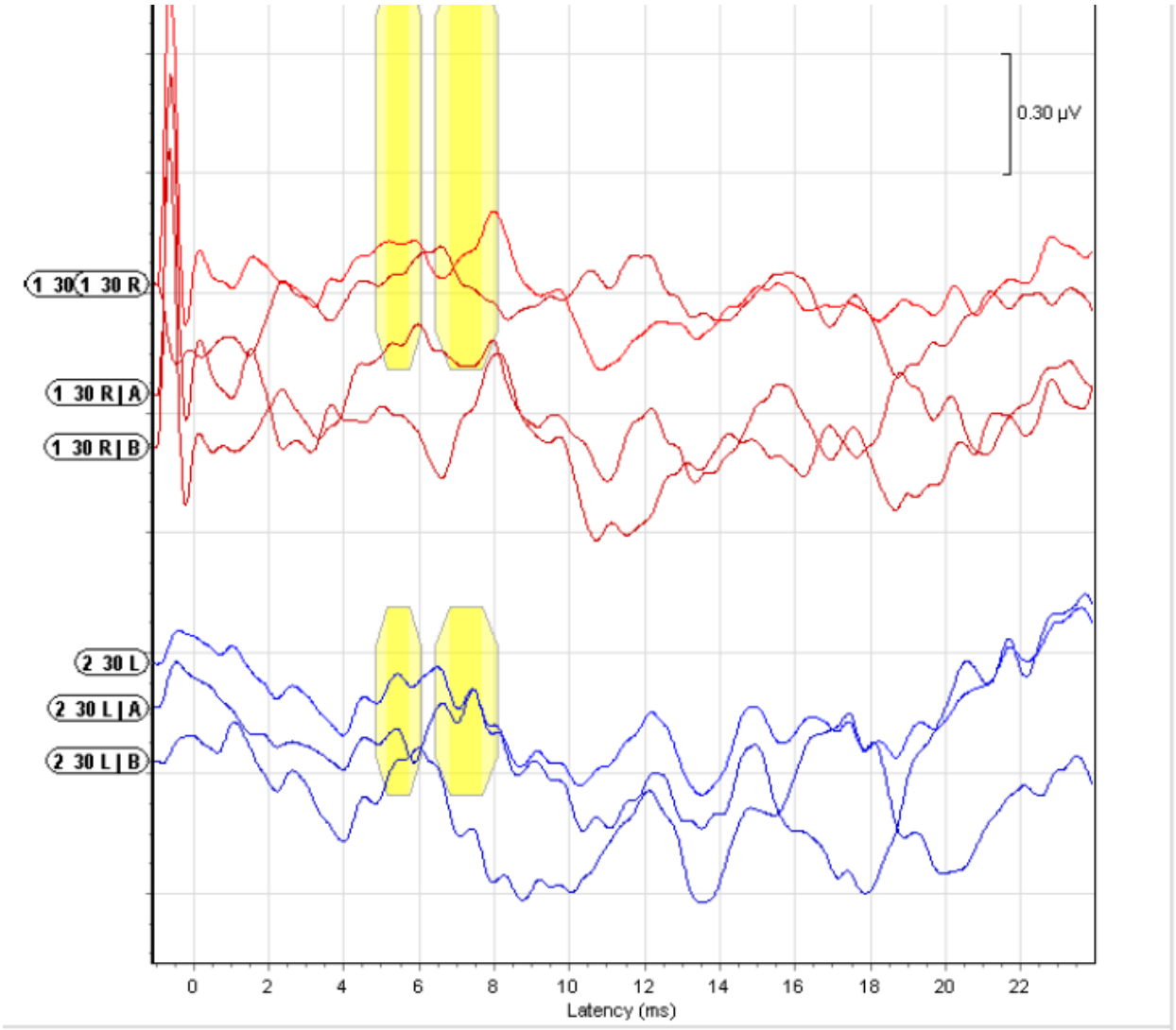

Image 6: ABR waveform from participant 76; fail in both ears.

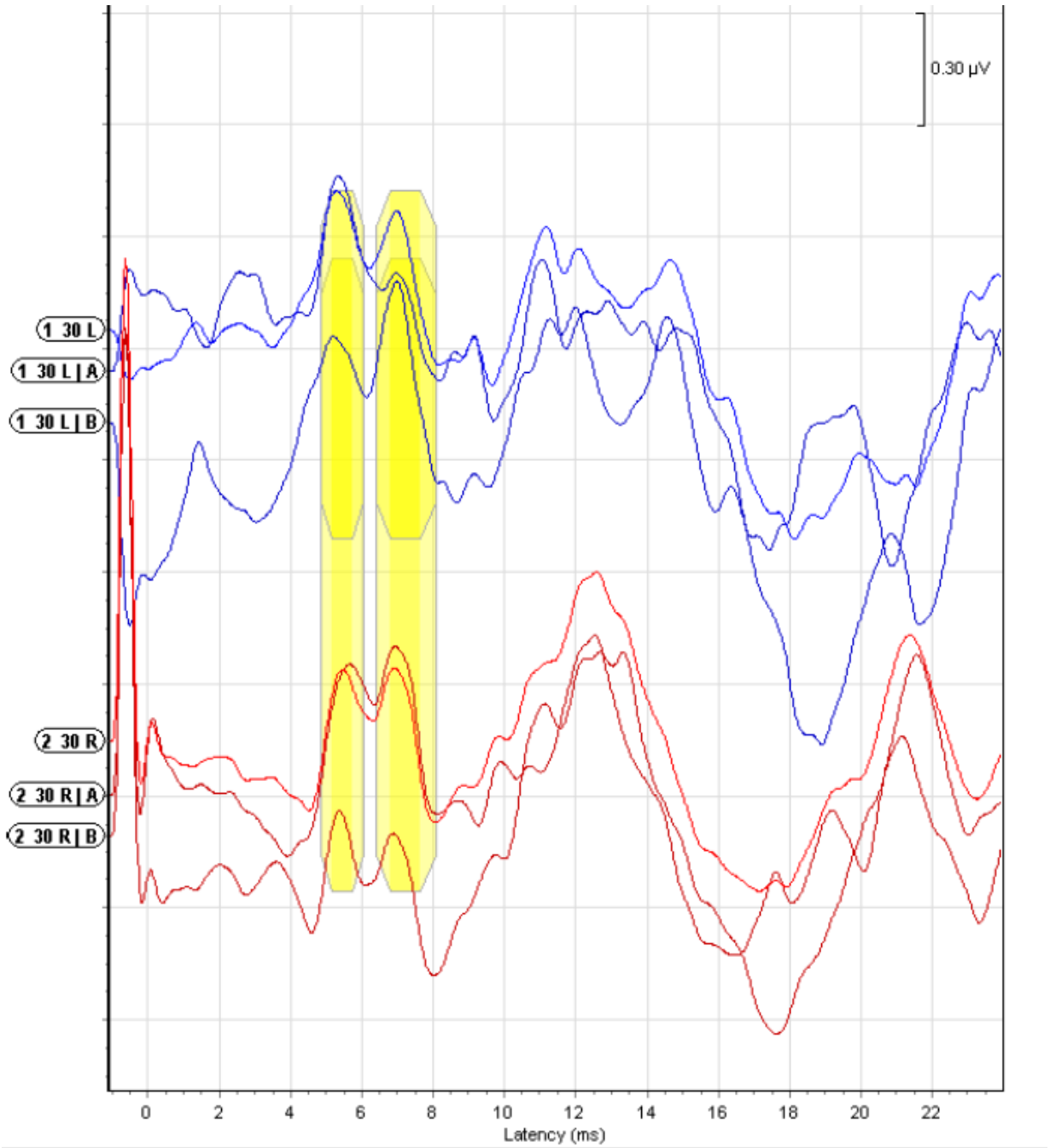

Image 7: ABR waveform from participant 161; pass in both ears; note PAM artifact.

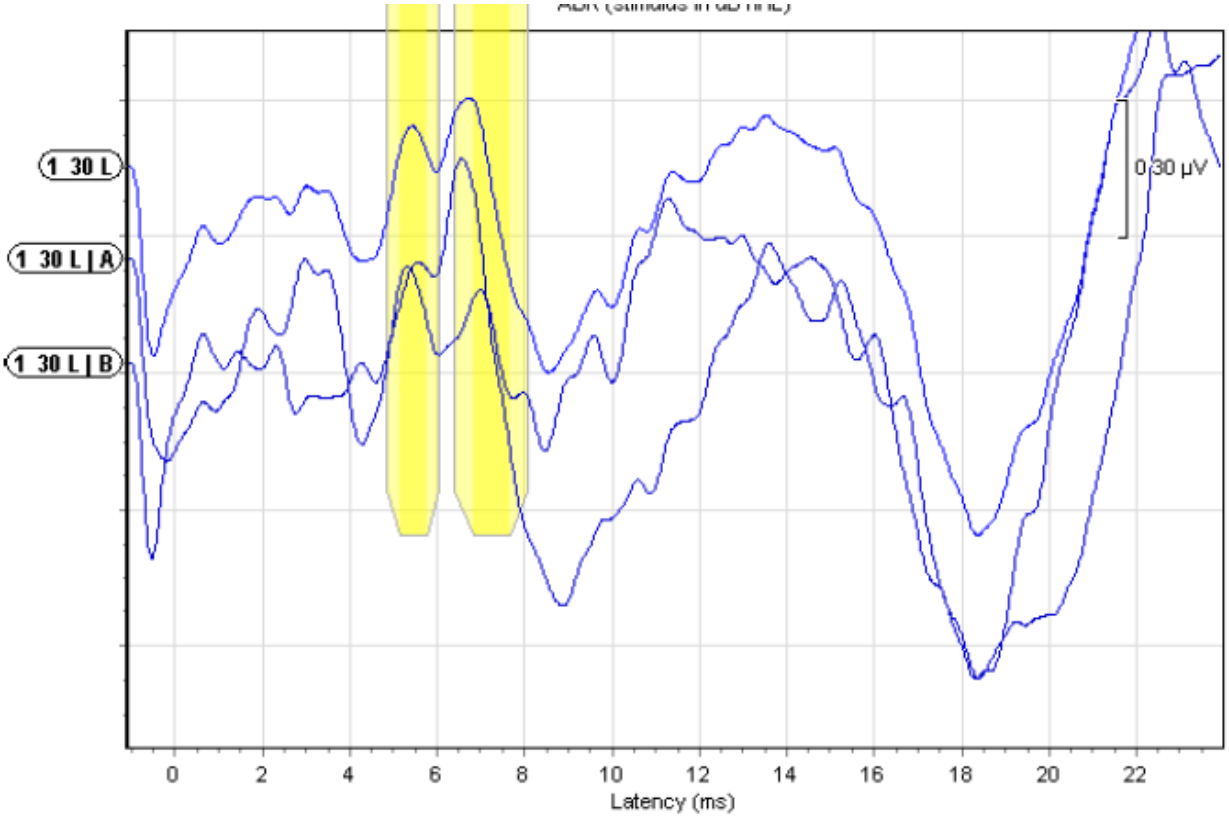

Image 8: ABR waveform from participant 156; pass in left; note PAM artifact.

CHAPTER 5
DISCUSSION

These results suggest that use of the Vivosonic Integrity™ ABR system as an auditory screener for difficult-to-test children is an effective means of reducing the referral rate due to an inability to test. Reducing the referral of normal hearing children for diagnostic assessment saves time, money, and other resources that would be spent on the comprehensive behavioral or electrophysiological assessments necessary to obtain information regarding their hearing status. In the current study, the time necessary to complete all 3 screeners (otoscopy, tympanometry, and ABR) on both ears was less than 15 minutes for most participants. This may be longer than the time needed when using a behavioral screener, but it is undoubtedly shorter than the time necessary to complete a comprehensive assessment, which may take from 40 minutes to more than 2 hours to complete (Karzon & Cho Lieu, 2006). Maintaining a short duration necessary to complete the screening is important to ensure cost effectiveness and acceptance of the screener, as discussed previously regarding guidelines for an effective screener (Wilson & Jungner, 1968).

As an example of possible cost savings, the Medicare Physician Fee Schedule (MPFS) sets a maximum amount that some health plans will reimburse for services. The current MPFS reimburses between $39.14-$63.65 for a comprehensive behavioral assessment (depending on procedures used) and $124.24 for a comprehensive assessment using auditory evoked potentials (ASHA, 2012). Therefore, even with the relatively small number of referrals eliminated in this study through use of the Vivosonic Integrity™ ABR device, hundreds of dollars could be saved and/or allocated for other purposes. This point shows a potential cost benefit of the device, which is a necessary component of an effective screener as outlined in the WHO guidelines (Wilson & Jungner, 1968). Additionally, obtaining a pass result on a hearing screening reduces the need for

sedated assessments that may be necessary to obtain diagnostic auditory information in this population. Finally, because of the non-compliance of some caregivers regarding recommendations for full assessments, the ability to obtain results using a non-invasive screener allows for access to information that the child, caregivers, and service-providers may otherwise go without. Knowing the hearing status of the child allows for more appropriate and specific therapy provision. Proper early intervention services may save thousands of dollars over the life of the child (Gross, 2007).

During completion of the current study, many important factors related to working with this population became apparent. First, the use of toys and videos to distract the child proved essential in data collection. The unique filtering of the Vivosonic Integrity™ ABR system allowed for the child to be moving to a certain degree while playing with a provided toy, and also allowed for the use of electronics (e.g. a computer displaying a video with audio) that would likely have raised acoustic and electrical noise to unsatisfactorily high levels with a traditional system. While many children resisted the application of the device, pulling electrodes off the skin and earphones out of the ear during setup, many calmed and effectively ignored testing after the setup was complete. This allowed for full data collection on children who, during behavioral screening, were never able to be distracted from the task at hand because their active attention was required. Although the researchers expected to be able to obtain results on children who were calm but could not perform the required tasks of behavioral screening (e.g. could not be conditioned to respond to stimuli), they found that results could also be obtained on some children who had challenging behaviors (e.g. non-compliance with setup and screening procedures). In fact, in some cases, a participant that ultimately passed the screener was noted to be crying and moving excessively during data collection. In other cases, participants who were

notably still and quiet during testing did not pass the screener. Therefore, movement and vocalization, in and of itself, did not appear to affect the pass/fail result of the screener. This was an unexpected and encouraging finding of the present study.

The personnel working with this population was also an important factor in whether or not screening was successful. The audiologist operating the Integrity™ must be comfortable with this population and persevere against certain obstacles. In many cases, setup of the device (attaching electrodes and inserting earphones) required several attempts as the child would continuously remove electrodes and earphones, or resist application in another manner (e.g. not sitting still). While it appeared that these children would be moving and resisting too much to complete testing, they would often calm and settle into watching the movie or playing with the toy provided as soon as the investigator was able to step away and begin data acquisition (i.e. after all electrodes were attached and earphones inserted). It was also beneficial in many cases to have a test assistant that was familiar with the child present during screening. The test assistant, usually a classroom teacher or aide, was able to use child-specific methods to increase compliance of the child. For example, some brought a snack for the child that was commonly used as a reinforcer during therapy. Another sang songs familiar to the child during setup. This individualized process allowed for quicker setup and data acquisition, and in some cases was essential to obtaining results.

If it is not possible or practical for the personnel performing the screening to have familiarity with a particular child, it is important that they have knowledge of the population to be screened in general. For example, many of the children screened in the present study were diagnosed with ASD. The personnel were aware that a change in routine may be difficult to this population. Therefore, care was taken to prepare the child for each step of the screening by

explaining what would happen (e.g. “Now I am going to wipe your forehead and put this sticker on it”). Due to the difficulty experienced applying electrodes in many cases, one may expect that removal would be desired by the child, and thus a simple, quick process. However, it was discovered that this was also met with resistance if the child was not prepared (i.e. “We’re all done. Now we are going to take off the stickers”). While these steps may seem inconsequential, in some cases they made the difference between whether or not the child was upset by the screening experience. In keeping with WHO guidelines for an effective screener, it is important that the procedures are acceptable to the population being screened (Wilson & Jungner, 1968). Therefore, the goal should always be to minimize distress to the child and to facilitate a positive screening environment.

Beyond the study questions, a few observations were made. First, some studies have found differences in ABR waveforms from children diagnosed with ASD. Rosenhall, Nordin, Brantberg, and Gillberg (2003), found that children with autistic disorder had significantly prolonged latencies of ABR waves when compared with typically developing control participants. This was true even of children with normal hearing. These differences were not found in the current study. However, because typically developing children were not assessed, a comparison cannot be made, although the results of children who passed the screening with ASD did fall within normal limits. Further studies in the area may be warranted to develop norms specifically for assessing ABR waves of children with ASD.

In 10 of 21 ABR waveforms collected in Part 2 of the study, a large peak was seen at approximately 13ms. The researchers suspect this was a Post-Auricular Muscle (PAM) artifact. PAM artifact typically occurs at a latency of 11.5-14 ms, and is seen most often when there is movement or tension of the neck muscles (Dus & Wilson, 1975). It is, therefore, not surprising

that the artifact was seen in the responses of participants in this study. It is an important point to note when performing ABR assessment of individuals who move excessively during testing, in order to prevent the peak from being falsely interpreted as a late Wave V. Examples of tracing with a suspected PAM artifact can be viewed in Images 7 and 8 (pages 41-42).

LIMITATIONS AND FUTURE STUDIES

The primary limitation of the current study is the small sample size. Further research is needed regarding the utility of the Vivosonic Integrity™ as a screening instrument for the difficult-to-test population. First, the current study should be repeated with a larger sample size to confirm the findings. Additionally, because the current study protocol used 30 dB nHL as a cut-off for normal hearing, it allowed the potential to miss some children with a minimal hearing loss (thresholds between 15 and 30 dB HL). Using a criterion of 20 dB nHL may improve the sensitivity of the measure. Finally, a study should be completed to determine the validity of the Vivosonic Integrity™ in determining pass/fail in the difficult-to-test population. A comparison between pass/fail rates obtained using the ABR screening equipment, and those found using a comprehensive behavioral or sedated ABR assessment should be used to confirm the accuracy of results obtained with the Vivosonic Integrity™ ABR. This information could be used to determine the sensitivity and specificity of the device as a hearing screener. This would further the confidence in using the equipment to rule out a concern of hearing loss.

CHAPTER 6
CONCLUSION

In conclusion, this study supports the use of the Vivosonic Integrity™ ABR system as a screening device for children who are difficult to test. Use of this equipment, in conjunction with behavioral screening methods, reduces the CNT rate and therefore the referral rate when compared with screening using behavioral methods alone. This would reduce the need for subsequent testing, including sedated procedures with associated risk and cost, and therefore would reduce costs associated with determining the hearing status of an individual. Further research is needed to replicate these results and to assess the accuracy of results obtained using the Vivosonic Integrity™ with the difficult-to-test population.

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APPENDIX
Parental Permission Forms

Form 1: Parental permission form for behavioral screening

The Ohio State University Parental Permission For Child's Participation in Research

Study Title: Utility of Vivosonic Integrity ABR system as a hearing screening device for children who are difficult to test

Researcher: Gail M. Whitelaw, Ph.D.

This is a parental permission form for research participation. It contains important information about this study and what to expect if you permit your child to participate.
Your child's participation is voluntary.
Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to permit your child to participate. If you permit your child to participate, you will be asked to sign this form and will receive a copy of the form.

Purpose:

To learn more about appropriate screening methods for children who are difficult to test.

Procedures/Tasks:

Children will be removed from their classroom to a separate test room in order to participate in the study.

They will first participate in a traditional behavioral hearing screening using standard methods. Students will listen to beeps through headphones and will be asked to raise their hand every time that they hear a beep. This is expected to take 5-10 minutes per child.

Then, otoscopy will be performed in which a researcher will look into your child's ears with an otoscope(lighted, hand-held microscope) to determine the presence or absence of an outer ear condition (e.g. ear wax buildup). This is expected to take 1-2 minutes per child.

Next, tympanometry will be performed to evaluate middle ear function. A soft probe will be placed in your child's ear canal and air pressure will be emitted. This experience is not painful and cannot cause any damage to the structures of the ear. Tympanometry results can indicate the potential presence of a middle ear condition (e.g. fluid in the ear). This is expected to take 1-2 minutes per child.

All results will be reported to you. If an outer or middle ear condition is suspected, referral for a medical evaluation will be provided. If your child does not pass the hearing screening, they will be offered the opportunity to participate in an alternate hearing screening, to occur at a later date. You will be provided information on this option, and asked to provide permission, before your child completes the alternate screening.

Duration:

Participation is expected to take a total of 5-14 minutes. Your child may leave the study at any time. If you or your child decide to stop participation in the study, there will be no penalty and neither you nor your child will lose any benefits to which you are otherwise entitled. If you choose to not provide permission for your child's participation, you will be provided with information regarding obtaining a hearing screening for your child elsewhere. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits:

There are no risks to participating in this study that are greater than those encountered in daily life. If your child does become distressed for any reason, and they are unable to be calmed, they will be withdrawn from the study, and allowed to leave the screening area and return to their typical daily activities.

The benefit is a free hearing test.

Confidentiality:

Efforts will be made to keep your child's study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your child's participation in this study may be disclosed if required by state law. Also, your child's records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

Incentives:

Study incentives are a free hearing screening.

Participant Rights:

You or your child may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you or your child is a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you and your child choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights your child may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

Contacts and Questions:

For questions, concerns, or complaints about the study you may contact Gail M. Whitelaw, Ph.D. at Whitelaw.1@osu.edu or 614-292-3405.

For questions about your child's rights as a participant in this study or to discuss other study-related concerns or complaints with someone who is not part of the research team, you may contact Ms. Sandra Meadows in the Office of Responsible Research Practices at 1-800-678-6251.

If your child is injured as a result of participating in this study or for questions about a study-related injury, you may contactGail M. Whitelaw, Ph.D. at Whitelaw.1@osu.edu or 614-292-3405.

Signing the parental permission form

I have read (or someone has read to me) this form and I am aware that I am being asked to provide permission for my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to permit my child to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form.

Printed name of subject

Printed name of person authorized to provide permission for subject

Signature of person authorized to provide permission for subject

Relationship to the subject

Date and time **AM/PM**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

Printed name of person obtaining consent	**Signature of person obtaining consent**
	AM/PM
	Date and time

Form 2: Parental permission form for ABR screening

The Ohio State University Parental Permission For Child's Participation in Research

Study Title: Utility of Vivosonic Integrity ABR system as a hearing screening device for children who are difficult to test

Researcher: Gail M. Whitelaw, Ph.D.

This is a parental permission form for research participation. It contains important information about this study and what to expect if you permit your child to participate.
Your child's participation is voluntary.
Please consider the information carefully. Feel free to discuss the study with your friends and family and to ask questions before making your decision whether or not to permit your child to participate. If you permit your child to participate, you will be asked to sign this form and will receive a copy of the form.

Purpose:

To determine whether the Vivosonic Integrity V500 ABR system is effective as a hearing screener for children who may be difficult to test.

Procedures/Tasks:

Children will be removed from their classroom to a separate test room in order to participate in the study.

They will first participate in a traditional behavioral hearing screening using standard methods. Students will listen to beeps through headphones and will be asked to raise their hand every time that they hear a beep.

Then, otoscopy will be performed in which a researcher will look into your child's ears with an otoscope (lighted, hand-held microscope) to determine the presence or absence of an outer ear condition (e.g. ear wax buildup).

Next, tympanometry will be performed to evaluate middle ear function. A soft probe will be placed in your child's ear canal and air pressure will be emitted. This experience is not painful and cannot cause any damage to the structures of the ear. Tympanometry results can indicate the potential presence of a middle ear condition (e.g. fluid in the ear).

You are receiving this document because your child did not pass the initial screening, and is therefore invited to participate in the Auditory Brainstem Response screening. On the scheduled date, your child will again be removed from class to participate in this alternate screening. First, otoscopy and tympanometry will be performed, as described above. Next, a hearing screening will be performed using an ABR test, as described below. The researchers of this investigation hope to show that children who are unable to perform traditional behavioral screenings can still be screened using ABR.

Screening will be performed using standard protocol with the Vivosonic Integrity V500 ABR system. This device is non-invasive, and records activity in the brainstem in response to sound. Recording of the response does not require any participation from your child, and this particular device does not even require that they sit still. Brainstem activity is picked up through electrodes, which are placed on the scalp. First your child's skin will be gently scrubbed in the locations where electrodes are to be placed. Four electrodes (stickers with metal buttons) will be placed on your child's scalp—two on the forehead, and one on the mastoid bone behind each ear. The electrodes are attached to a small backpack (see photo below) via three wires, which clip to the metal electrode buttons. The processor will be placed on your child to be worn like a backpack (see below and the enclosed literature), worn around the neck like a necklace, or placed beside you child on a table, depending on whatever will be most comfortable and provide adequate mobility. Once the processor is secured onto your child, soft earplug-like headphones will be inserted into their ear canals. Then, they will be provided with a toy and will be allowed to roam the room and play, or watch a video, while screening occurs (approximately 15-30 minutes). During this screening period, your child will hear rapid clicking sounds through the soft earphones. The electrodes will record brain waves, and transmit this information to a computer, where the researchers will interpret it to determine whether or not it indicates normal hearing in your child. Following this screening, your child will be finished with their participation, and they will return to their regularly scheduled activities.

All results will be reported to you. If an outer or middle ear condition is suspected, referral for a medical evaluation will be provided. If your child fails the ABR hearing screening, they will be referred for a complimentary comprehensive audiologic evaluation to determine the presence or absence of a hearing loss.

Duration:

Participation is expected to take a total of 17-34 minutes. Your child may leave the study at any time. If you or your child decide to stop participation in the study, there will be no penalty and neither you nor your child will lose any benefits to which you are otherwise entitled. If you choose to not provide permission for your child's participation, you will be provided with information regarding obtaining a hearing screening for your child elsewhere. Your decision will not affect your future relationship with The Ohio State University.

Risks and Benefits:

Only minimal risks are expected as a result of study participation, in that your child may become anxious due to the unfamiliar task. In order to reduce this discomfort, several measures will be taken. First, all tasks will be performed in a room in which students are familiar so that they may feel more comfortable during participation. Instructors and other professionals that are familiar with your child will be encouraged to remain in the room during screening. Finally, your child will be provided with a toy and allowed to roam around the room during ABR screening so that they may be distracted from the task at hand and not feel confined. If your child is unable to be comforted using the above methods, they will be withdrawn from the research and allowed to leave the screening area and resume their typical daily activities.

The benefits to your child are that his/her hearing status, and the status of their outer and middle ear, may be determined. As stated previously, referrals will be made if your child does not pass the hearing screening or if outer or middle ear conditions are expected. A comprehensive audiologic evaluation will be offered at no charge to you. If a hearing loss is confirmed, all efforts will be made to ensure that the most appropriate interventions are provided. Hearing loss is associated with decreased academic, social, and emotional functioning, and identifying and treating a hearing loss has the potential to provide great benefit to an effected child.

Confidentiality:

Efforts will be made to keep your child's study-related information confidential. However, there may be circumstances where this information must be released. For example, personal information regarding your child's participation in this study may be disclosed if required by state law. Also, your child's records may be reviewed by the following groups (as applicable to the research):

- Office for Human Research Protections or other federal, state, or international regulatory agencies;
- The Ohio State University Institutional Review Board or Office of Responsible Research Practices;
- The sponsor, if any, or agency (including the Food and Drug Administration for FDA-regulated research) supporting the study.

Incentives:

Study incentives are a free hearing screening and referral for a complimentary comprehensive audiologic evaluation if appropriate. Additionally, your child will be allowed to keep the provided toy.

Participant Rights:

You or your child may refuse to participate in this study without penalty or loss of benefits to which you are otherwise entitled. If you or your child is a student or employee at Ohio State, your decision will not affect your grades or employment status.

If you and your child choose to participate in the study, you may discontinue participation at any time without penalty or loss of benefits. By signing this form, you do not give up any personal legal rights your child may have as a participant in this study.

An Institutional Review Board responsible for human subjects research at The Ohio State University reviewed this research project and found it to be acceptable, according to applicable state and federal regulations and University policies designed to protect the rights and welfare of participants in research.

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Signing the parental permission form

I have read (or someone has read to me) this form and I am aware that I am being asked to provide permission for my child to participate in a research study. I have had the opportunity to ask questions and have had them answered to my satisfaction. I voluntarily agree to permit my child to participate in this study.

I am not giving up any legal rights by signing this form. I will be given a copy of this form**.**

Printed name of subject

Printed name of person authorized to provide permission for subject

Signature of person authorized to provide permission for subject

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Date and time **AM/PM**

Investigator/Research Staff

I have explained the research to the participant or his/her representative before requesting the signature(s) above. There are no blanks in this document. A copy of this form has been given to the participant or his/her representative.

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Signature of person obtaining consent

Date and time **AM/PM**